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EXAMINER	
ROZANSKI, MICHAEL T	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,261	THOMAS ET AL.	
	Examiner	Art Unit	
	MICHAEL T. ROZANSKI	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44 and 46-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-15, 17-23, and 26-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner (US Patent No. 5,154,179), in view of Filler (US Patent No. 5,948,384).

With regards to claims 1, 4, 7, 8, 14, 15, 20, 28, 32-34, Ratner discloses a visibility enhancement device that is inserted into the body. The device comprises a flexible marker member with a lumen (fig. 3), which is composed of biological stable substance and is insertable into the body cavity (col.3, lines 50-64). The marker

member comprises a proximal end (fig. 3, ref. 23), a distal end (fig. 3, ref. 24) and an interior portion (fig. 3, ref. 22c). An imaging material is retained into the marker member and it does not directly contact with the internal body (claim 9 and fig. 3).

With regards to claims 2, 3, 5, 12 and 31, Ratner discloses that the imaging material is injected into the marker member by using a catheter (fig. 3, ref.46). The imaging material is movably positioned and dispersed longitudinally in a homogeneous manner in the interior of the marker member. (col. 6, lines 19-25), (col. 10, lines 2-5) and (fig. 3).

With regards to claims 6, 13 and 29, Ratner discloses that the lumen is composed of biological stable material, which is capable of translating the detectable signal to give visual representation (col. 4, lines 24-34).

With regards to claims 9, 18, 19, 35 and 36, Ratner discloses that the marker member is composed of an interior lumen (fig.6, ref. 57) and an exterior lumen (fig.6, ref.56). The interior and exterior lumen defines a space in between and the imaging material is contained external to the interior lumen (fig.6) and also internal to the interior lumen (col. 7, lines 35-39).

With regards to claims 11 and 22, Ratner discloses that the device is adapted to be inserted into anatomical structures including urinary track (col. 8, lines 62-69).

With regards to claim 37, Ratner discloses that the interior lumen contained a second distinct imaging material than the imaging material contained in the exterior lumen (co1.10, lines 24-46).

With regards to claim 17, Ratner discloses that the marker member contains

imaging material that comprises a gel (col.6, lines 12-14).

Ratner discloses the invention describes above. Ratner also discloses that marker member can also contain different kinds of imaging materials (col. 9, lines 4-32). However, Ratner fails to disclose using a radiopharmaceutical material as imaging material that comprises radioisotopes and the marker member is detectable by single photon emission computed tomography detector.

Filler discloses diagnostic marker that are injected into the body. The marker includes radioisotopes that are detectable by using single photon emission computed tomography detector (col.3, lines 64-67). The markers are injected into the body using a catheter (col. 14, lines 14-19). Filler further discloses that the radioisotope produces a decay signal (col. 11, lines 9-14)in centimeter range (col. 14, lines 38-41), and emits gamma particles in the range between 30 KeV to 1000 KeV (col. 11, lines 47-54). Filler further discloses the use of MRI contrast agents (col. 25, lines 51-56). The MRI contrast agents are selected from the group consisting supermagnetic or paramagnetic compounds (col. 29, lines 48-50) and gadolinium compound (col. 8, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Ratner's visibility enhancement device and use radioisotopes that decays and are detectable by single photon emission computed tomography detector as taught by Filler for obtaining better image contrast.

Claims 10 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Filler as applied to claims 9 and 37 above, and further in view of

Valley et al (US Patent No. 5,766,151).

Ratner and Filler discloses the invention described above. However, Ratner and Filler fail to disclose inflation of the interior lumen.

Valley discloses a catheter based system for the infusion of cardioplegic agent into the patient coronary arteries. The catheter based system comprises a catheter with interior inflating lumen, which delivers the inflation fluid and results in the inflation of the balloon (col. 8, lines 41-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use a catheter with inflating lumen as taught by Valley to inflate the lumen and blocks the blood flow of the veins in which the catheter is placed for obtainning better images during static motions in the veins.

Claims 16, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Filler as applied to claims 15 and 20 above, and further in view of Unger et al (US Patent No. 5,736,121).

Ratner and Filler disclose the invention described above. However, Ratner and Filler fail to disclose CT contrast agent. Unger discloses a contrast agent that can be used with computer tomography (abstract). The contrast agent comprises propylene glycol (col. 14, lines 34-38) and iohexol (co1.30, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use the

contrast agent disclose by Unger to be able to obtain images by using different contrast agents for obtaining improved diagnostic results.

Claims 39, 40, 41, 43, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner (US Patent No. 5,154,179), in view of Bankiewicz et al. (US Patent No. 6,309,634).

Ratner discloses the invention described above. However, Ratner fails to disclose registration of first and second image.

Bankiewicz et al teach of placement of a device at a targeted site involving registration of PET and MRI images through the use of external fiducial markers (col 32, lines 14-16).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visualization device and include image registration to register images acquired from different image modalities as taught by Bankiewicz for obtaining better quality of images for advance diagnostic purposes.

Claims 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Bankiewicz as applied to claim 39 above, and further in view of Driscoll, Jr. et al. (US Patent No. 5,926,568).

Ratner and Bankiewicz disclose the invention described above. However, Ratner and Bankiewicz fail to disclose verification of image registration.

Driscoll discloses a method and apparatus for verifying identity using of image

correlation. The method includes verifying image registration (col. 10, lines 33-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use verification of image registration as taught by Driscoll for precise acquisition of the data.

Claims 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Bankiewicz and Driscoll Jr. et al. as applied to claim 42 above, and further in view of Chaney et al. (US Patent No. 5,926,568).

Ratner, Bankiewicz and Driscoll Jr. et al. disclose the invention described above. However, Ratner, Bankiewicz and Driscoll Jr. et al. fail to disclose registration of the images.

Chaney discloses a method of registering radiotherapy images (col. 3, lines 36-39). The method includes automatically registration of two images (col. 5, lines 63-68) by using image registration algorithm (col. 20, lines 32-34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use image registration method as taught by Chaney for obtaining high resolution images.

Claims 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Bankiewicz as applied to claim 39 above, and further in view of Chaney et al. (US Patent No. 5,926,568).

Ratner and Bankiewicz disclose the invention described above. However, Ratner

and Bankiewicz fail to disclose alignment of the images.

Chaney discloses a method of registering radiotherapy images (col. 3, lines 36-39). Chaney further discloses the alignment of subsequent images (col. 7, lines 7-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use image alignment method as taught by Chaney for obtaining high quality of images without distortion.

Response to Arguments

Applicant's arguments filed 2/24/09 have been fully considered but they are not persuasive. In regard to claims 1, 20, and 28, Applicant argues that the Ratner/Filler combination does not render the current invention obvious. Applicant notes that Ratner describes a device that carries imaging material that is detectable by MRI and that the material may also include radiopaque material such that it can be observed under x-rays, in addition to being detectable by MRI. Furthermore, Applicant notes that Filler is directed to particulate agents for use in diagnostics and therapy, including diagnostic imaging and are detectable by gamma detectors, scintography, or SPECT. The Examiner does not disagree with these teachings.

Applicant argues that since particulate agents are not used for MRI, there is no motivation to combine. The Examiner diagrees with this assertion. The skilled artisan would not attempt to image the particulate agents with MRI. Ratner discloses the claimed structure with imaging material that is detectable by MRI and/or x-ray, but does

not disclose an imaging material containing a radiopharmaceutical material detectable by PET or SPECT. Filler teaches of a marker with radiopharmaceutical material that detected from within the body with SPECT, for example. The skilled artisan would realize that if the radiopharmaceutical material were placed in the structure of Ratner that an imaging modality such as SPECT would be used to detect the image. Therefore, Examiner submits that it is not critical that Ratner only discloses imaging material detectable by MRI and/or x-ray.

In regard to claim 39, Applicant has provided amendments that change the scope of the claim. The secondary reference used in the previous rejection is now replaced by Bankiewicz, which teaches PET-MRI image registration.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,738,096 to Ben-Haim teaches that incorporating a catheter with a radioactive marker would be suitable for SPECT (col 28, lines 15-17).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

MR